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ATTORNEY DOCKET NO.: 2002834-0222 (Bacterial Delivery DIV1)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Caplan et al. Examiner: Not yet assigned  
Serial No.: 10/728,051 Art Unit: Not yet assigned  
Filing Date: December 4, 2003  
Title: Microbial Delivery System

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

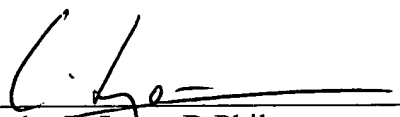
**TRANSMITTAL LETTER**

Enclosed are the following documents:

1. Form PTO-1449 (1 page);
2. Information Disclosure Statement (6 pages);
3. Statement of Limited Recognition (1 page);
4. Cited Art (5 references); and
5. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

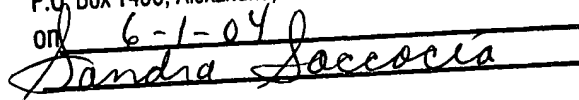
Respectfully submitted,

  
Charles E. Lyon, D.Phil.  
Agent for Applicant  
Limited Recognition Under 37 CFR §10.9(b)

Choate, Hall & Stewart  
Exchange Place  
53 State Street  
Boston, MA 02109  
(617) 248-5000  
(617) 248-4000

Dated: June 1, 2004

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on 6-1-04





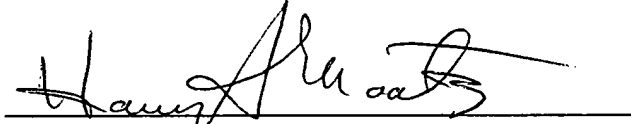
**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE  
UNITED STATES PATENT AND TRADEMARK OFFICE**

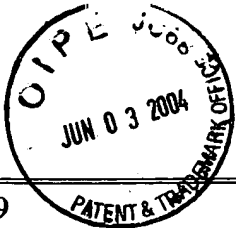
**LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)**

Charles Lyon is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of the Choate, Hall & Stewart law firm to prepare and prosecute patent applications wherein the patent applicant is the client of the Choate, Hall & Stewart law firm, and the attorney or agent of record in the applications is a registered practitioner who is a member of the Choate, Hall & Stewart law firm. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Charles Lyon ceases to lawfully reside in the United States, (ii) Charles Lyon's employment with the Choate, Hall & Stewart law firm ceases or is terminated, or (iii) Charles Lyon ceases to remain or reside in the United States on an H1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the United States Patent and Trademark Office.

**Expires: December 1, 2004**

  
\_\_\_\_\_  
Harry I. Moatz  
Director of Enrollment and Discipline



<b>PTO-1449</b> <b>(REV. 8-83)</b>  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET: 2002834-0222	IN RE APPLICATION NO.: 10/728,051
		APPLICANT: Caplan, et al.	
		FILING DATE: December 4, 2003	GROUP:

**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass

**U.S. PATENT APPLICATIONS**

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	EP 0 080 806	Europe	08 June 1983		
	WO 98/44096	PCT	08 October 1998		
	WO 96/14876	PCT	23 May 1996		

**OTHER DOCUMENTS**

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Hansen, "Vaccination with Heat-Killed Listeria as Adjuvant Reverses Established Allergen-Induced Airway Hyperreactivity and Inflammation: Role of CD8 <sup>+</sup> T Cells and IL-18", <i>The Journal of Immunology</i> , 164: 223-230, 2000.
	Mekalanos, "Bacterial Mucosal Vaccines" in Genetically Engineered Vaccines, Edited by Ciardi et al., Plenum Press, Pages 43-50, 1992.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



ATTORNEY DOCKET NUMBER: 2002834-0222 (Bacterial Delivery DIV1)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Caplan et al.  
Serial No.: 10/728,051  
Filing Date: December 4, 2003  
Title: MICROBIAL DELIVERY SYSTEM

Examiner: Not yet assigned  
Art Unit: Not yet assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- [ ] An *original* Information Disclosure Statement; or  
[X] A *supplemental* Information Disclosure Statement.

<b>Certificate of Mailing</b>	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
6-1-04	<i>Sandra Saccoccia</i>
Date	Signature
Sandra Saccoccia	
Typed or Printed Name of person signing certificate	

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:
- ☐ Includes one or more translations of a non-English citation.

## Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .


The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

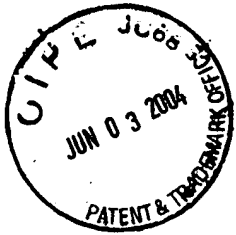
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Dated: 6-1-04



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**Expires: May 16, 2004**

Harry I. Moatz  
Director of Enrollment and Discipline